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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/255,655	02/23/1999	MADS LIENDGAARD VIGH	02405.0167	8849

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EXAMINER
OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 08/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/255,655	VIGH ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Arguments

The following is in response to the appeal brief filed 1/07/02:

An action on the merits of claims 1-12 is contained herein below.

Withdrawal of finality

Pursuant to an appeals conference, the finality of the rejection of the last office action is withdrawn.

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 - 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Zehner et al. (Zehner), U.S. Patent no. 5,447,917.

Claims 13-17 are drawn to a method for inducing production of butyrate by bacteria in the human colon comprising administering an effective amount of D-tagatose.

Claims 18 - 22 are drawn to a method for stimulating the growth of lactobacilli and lactic acid bacteria comprising administering D-tagatose to a human in an amount effective to selectively stimulate growth of lactobacilli and lactic bacteria in the human colon.

Zehner anticipates the claims cited supra as it teaches (columns 2-4, claims 1-3) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the claimed daily administration of 5 to 30 grams. The stimulation of lactobacilli and the production of butyrate in the human colon is inherently achieved in Zehner via the administration of the D-tagatose

art did disclose a method of inoculating a plant with "pseudomonas cepacia type Wisconsin 526," which inherently possessed nematode-inhibiting activity an inherent effect not set forth in the prior art (the inherent nematode inhibiting activity was set forth in appellant's specification, not the prior art). Similarly, in the instant claims, the method of administration, the compound and the subject are identical to that set forth in the prior art of Zehner; reminiscent of *Novitski*, the only difference is that the inherent effect, stimulation of lactobacilli and the production of butyrate in the human colon, is not stated in the prior art of Zehner.

Applicant argues that Zehner does not teach and does not recognize that D-tagatose was effective to "selectively" induce butyrate production and to "selectively" stimulate the growth of lactobacilli. As cited above, Per *Ex parte Novitski*, 26 USPQ2d 1389 (1993), a claimed method of administering a known compound to a subject to achieve an effect not stated in the prior art is anticipated when the differently claimed effect is an inherent feature of the known compound previously administered to the same subject in the prior art, thus the fact that the induction of butyrate and the stimulation of the growth of lactobacilli is not mentioned in Zehner does not mean that there is no inherency. If Zehner taught the induction of butyrate and the stimulation of the growth of lactobacilli, the rejection would not be based on inherency, but anticipation by the literal teachings of the prior art.

Applicant further argues that there is no inherency because the populations/subjects treated are different. This differentiation is based on the assumption that the teachings of Zehner are limited to a diabetic population. However, the teachings of Zehner are not limited to diabetic populations and the population/subjects as claimed are open to any subject wherein Tagatose is administered within the claimed dosage range. Zehner teaches (columns 2-4, claims 1-3) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the claimed daily administration of 5 to 30 grams. Zehner also teaches that diabetes is just one affect of the condition of hyperglycemia. Zehner teaches avoiding the condition of hyperglycemia because of the negative effects associated with the increase in blood sugar levels, which is not restricted to a certain patient population and relevant to the dietary habits of both the

claimed subjects and those of the prior art. The treatment of hyperglycemia is targeted to control impaired glucose tolerance as well, which is not synonymous with diabetes (see col. 1, lines 25-27). Zehner also teaches the use of D-tagatose to reduce the formation of advanced glycosylated end products which may form from hyperglycemia, wherein the avoidance of these end products is a benefit conferred to both diabetic and non-diabetic subjects. The subjects present in Zehner also are comparable to the claim language in that sugars such as sucrose and glucose are restricted in their diets because they elevate blood sugar (col. 1, , lines 65 – 67), thus comparably, the population of Zehner is in need of administration of the same sugar within the same dosage range to confer a beneficial effect.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.